EXHIBIT L

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327** **JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: ***Margaret Stubblefield v Ethicon, Inc., et al*** ***Case No. 2:12-cv-00842***	

Case Specific Report of Shelby F. Thames, Ph.D.

Margaret Stubblefield v. Ethicon

March 18, 2016

At my direction, Dr. Kevin Ong of Exponent Labs received a tissue and mesh sample explanted from Margaret Stubblefield, herein labeled as Stubblefield 1.3.1. The explant was received in 10% neutral buffered formalin. Dr. Ong divided the sample, rinsed and soaked it in distilled water, dried it once again and sent it to me via overnight delivery before any tissue removal or cleaning steps were undertaken. I received the 'before cleaning' sample labeled Stubblefield 1.3.1, along with an exemplar Gynemesh sample, (GPSL, Lot CKB435) an Ethicon product made of Prolene, the same material at issue in this litigation.

Upon receipt, the sample was examined via Light Microscopy (LM), Fourier Transform Infrared Microscopy (FTIR-Micro), and Scanning Electron Microscopy (SEM). The initial data acquired was designated as "Before Cleaning" and recorded. The explant was returned to Dr. Ong with my request to clean the explants according to the cleaning process I developed (see Figure 1). After cleaning through steps 1 and 2 of the aforementioned protocol, the "After Cleaning 1" explant was returned to me for further

analyses. This process was repeated as noted below in the cleaning protocol detailed in Figure 1. Explant examinations were conducted at the following intervals:

- Before Cleaning
- After Cleaning 1
- After Cleaning 2
- After Cleaning 3
- After Cleaning 4
- After Cleaning 5

Sample Name	1st Step	2nd Step	3rd Step	4th Step	5th Step	6th Step	7th Step	8th Step	9th Step
Stubblefield 1.3.1	Distilled water. Spray rinse; soak 1 h; spray rinse	Desiccation drying,1 h. Followed by SEM	Distilled water. Water bath (70 ˚C), 42 h; spray rinse	6-14% NaOCl. Shaker, 15 min	Distilled water. Spray rinse; soak 1 h; spray rinse	Desiccation drying, 1h. Followed by SEM	Distilled water. Water bath (70 ˚C), 40 h	6-14% NaOCl. Shaker, 1 h	6-14% NaOCl. Ultrasonic bath, 1 h
		Before Cleaning				**After Cleaning 1**			

Sample Name	10th Step	11th Step	12th Step	13th Step	14th Step	15th Step	16th Step	17th Step	18th Step
Stubblefield 1.3.1	Distilled water. Spray rinse, ultrasonic	Desiccation drying,1 h. Followed by SEM	6-14% NaOCl. Shaker, 4 h	6-14% NaOCl. Ultrasonic bath, 2 h	Distilled water. Spray rinse, ultrasonic	Desiccation drying,1 h. Followed by SEM	Distilled water. Water bath (70 ˚C), 30 h	0.8 mg/ml Proteinase K. Water bath (58 ˚C),	0.8 mg/ml Proteinase K. Ultrasonic
		After Cleaning 2				**After Cleaning 3**			

Sample Name	19th Step	20th Step	21st Step	22nd Step	23rd Step	24th Step	25th Step
Stubblefield 1.3.1	Distilled water. Spray rinse, ultrasonic bath 1h, spray rinse.	Desiccation drying, 1 h. Followed by SEM	Distilled water. Water bath (70 ˚C), 48 h	6-14% NaOCl. Shaker, 17 h	6-14% NaOCl. Ultrasonic bath, 2 h.	Distilled water. Spray rinse, ultrasonic bath 1h, spray rinse.	Desiccation drying,1 h. Followed by SEM
		After Cleaning 4					**After Cleaning 5**

Figure 1. Stubblefield 1.3.1 – Cleaning Protocol

Before Cleaning

The “before cleaning” samples were examined via light microscopy (LM), scanning electron microscopy (SEM), and Fourier transform infrared microscopy (FTIR-Micro). Figure 2 illustrates the appearance of a pristine Gynemesh sample, (GPSL, Lot CKB435). Light microscopy analysis (Figure 3) depicts the extent to which the explanted mesh was tissue encapsulated within an opaque to white tissue mass.

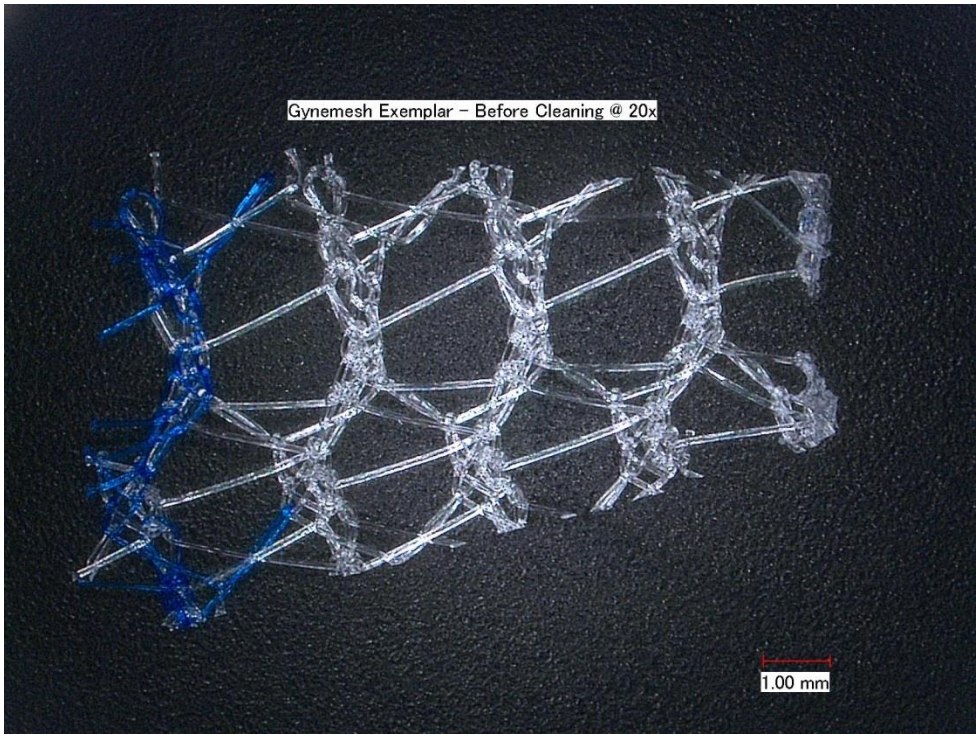

Figure 2. Pristine Gynemesh (GPSL, Lot CKB435) – Before Cleaning

Figure 3. Stubblefield 1.3.1 sample – Before Cleaning

Higher magnification (200X) shows Prolene fiber as it is encased within dry, and cracked proteinaceous layer as noted in Figures 4 and 5, and whose structures were confirmed by FTIR microscopy.

These data alone are sufficient to defeat plaintiff's consistent and incorrect tenet of *in-vivo* Prolene degradation. Plaintiffs contend, without scientific evidence, Prolene degrades *in vivo* with concomitant cracking, loss of physical integrity and toughness, loss of molecular weight, embrittlement, and so forth. Plaintiffs allege Prolene undergoes surface cracking leading to property losses. However, if one simply examines Figures 4 and 5, it is obvious surface cracking and peeling occurs on both the clear (unpigmented) and blue (pigmented) Prolene fibers. Plaintiffs contend surface cracking material is degraded Prolene. However, this cannot be true. For instance, if surface cracking and peeling material is degraded Prolene, the unpigmented and supposedly degraded Prolene fibers would be clear. Likewise, the blue and pigmented degraded Prolene fibers would be blue. However, LM data shows unequivocally the composition of the material peeling on both the clear Prolene fiber and pigmented Prolene fiber is translucent under light microscopy.

This finding does not support plaintiff's theory that the cracked material is degraded Prolene. To the contrary, LM data are proof positive the cracked and peeling product is not Prolene, but proteinaceous in composition.

To further confirm this tenet, we turned to chemical structure analysis by FTIR microscopy and scanning electron microscopy (SEM).

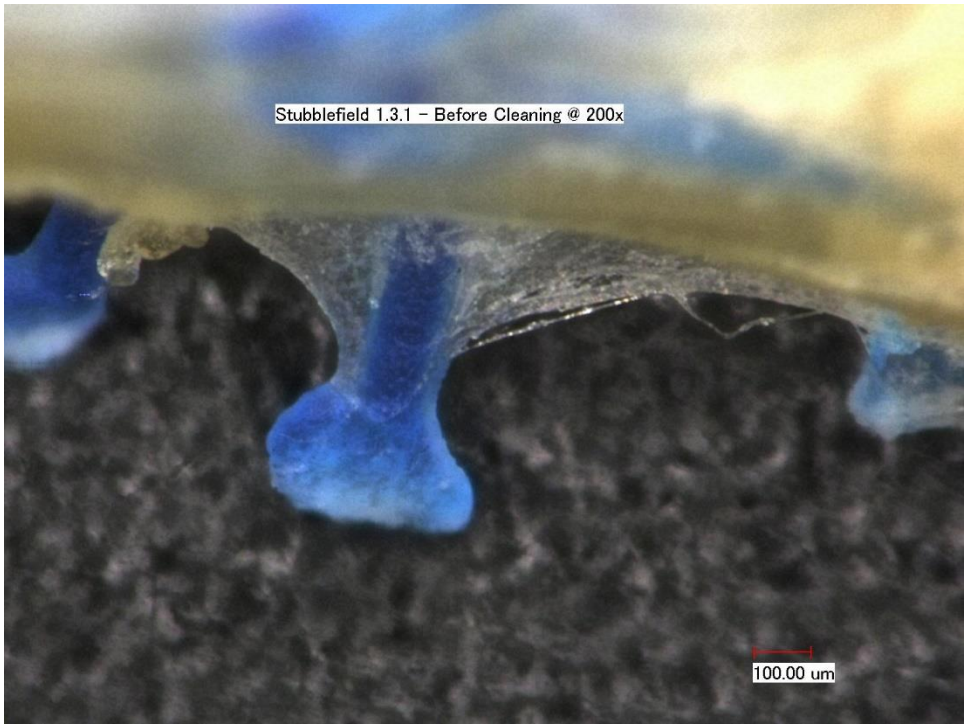

Figure 4. Stubblefield 1.3.1 – Before Cleaning @ 200X

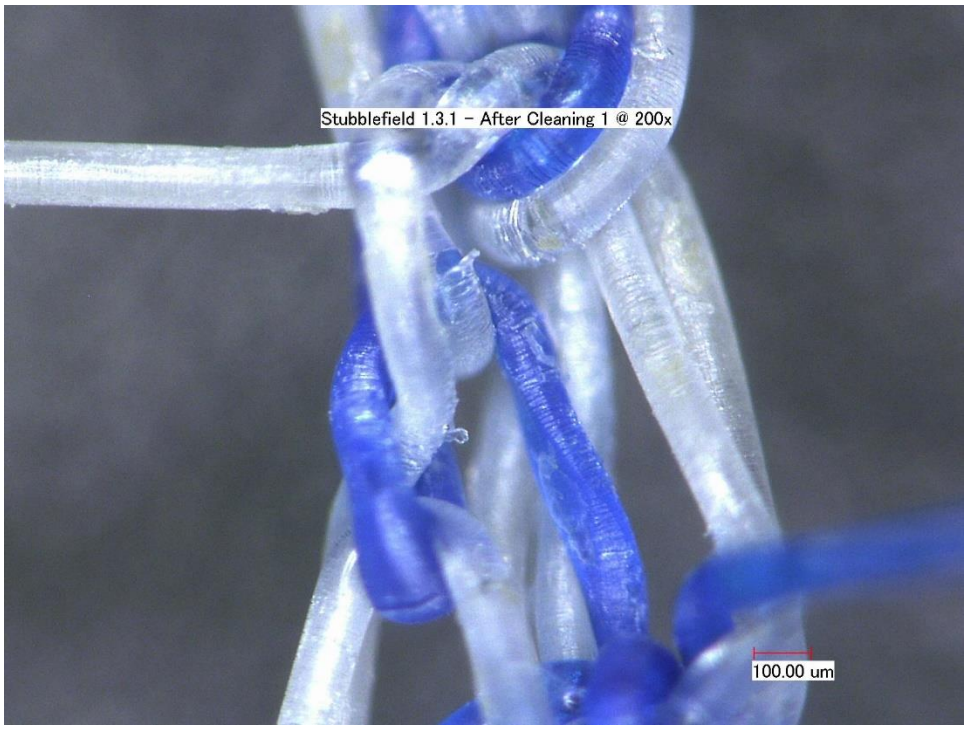

Figure 5. Stubblefield 1.3.1 – After Cleaning 1 @ 200X

Chemical Structure Analysis by FTIR Spectroscopy

It is also important to note the identical translucent/clear nature of the cracked and peeled material of both blue and clear fibers. The flaked layer on the blue fiber is clear to translucent, not blue, again confirming its composition is not Prolene (Stubblefield 1.3.1). If it is degraded Prolene, it would be blue and it is not. Likewise, if the flaked material on the clear fiber were Prolene it would be clear. Both fiber flakes, however, are translucent and thus are not clear or blue Prolene.

FTIR analyses of the flaked and peeling material from both clear and blue fibers are consistent, and further confirms the cracked and peeling materials are proteins, not Prolene.

The presence of the thin, remaining translucent protein layer on the Prolene fiber after flesh has been mechanically removed proves strong protein adsorption and a strong adhesive bond formation between the adsorbed proteins and Prolene. The cleaning protocol to which these samples were subjected will confirm, by scientifically collected evidence and experimentation, the difficulty in removing all adsorbed proteins from Prolene.

The “Before Cleaning fiber” FTIR spectrum (Figure 6) shows spectral components of both polypropylene and proteins as noted by the highlighted 3291 and 1651 cm^{-1} frequencies, respectfully. These absorption frequencies are attributed to the protein amide N-H stretching in the 3300 cm^{-1} region and amide I carbonyl stretching in the region of 1600-1690 cm^{-1} as noted by Kong *et al*., respectively.[1] Polypropylene

absorption frequencies are also present at 1449 and 1378 cm^{-1} due to penetration of the IR beam through both the protein layer and into the polypropylene fiber.

FTIR spectroscopy confirms tissue decomposition products comprised of fats and lipids surrounding Prolene fibers. It is known the process of tissue decomposition produces a number of fatty acids and esters as reported by Notter and Stuart.[2,3] Similar decomposition products were observed in other explants received.

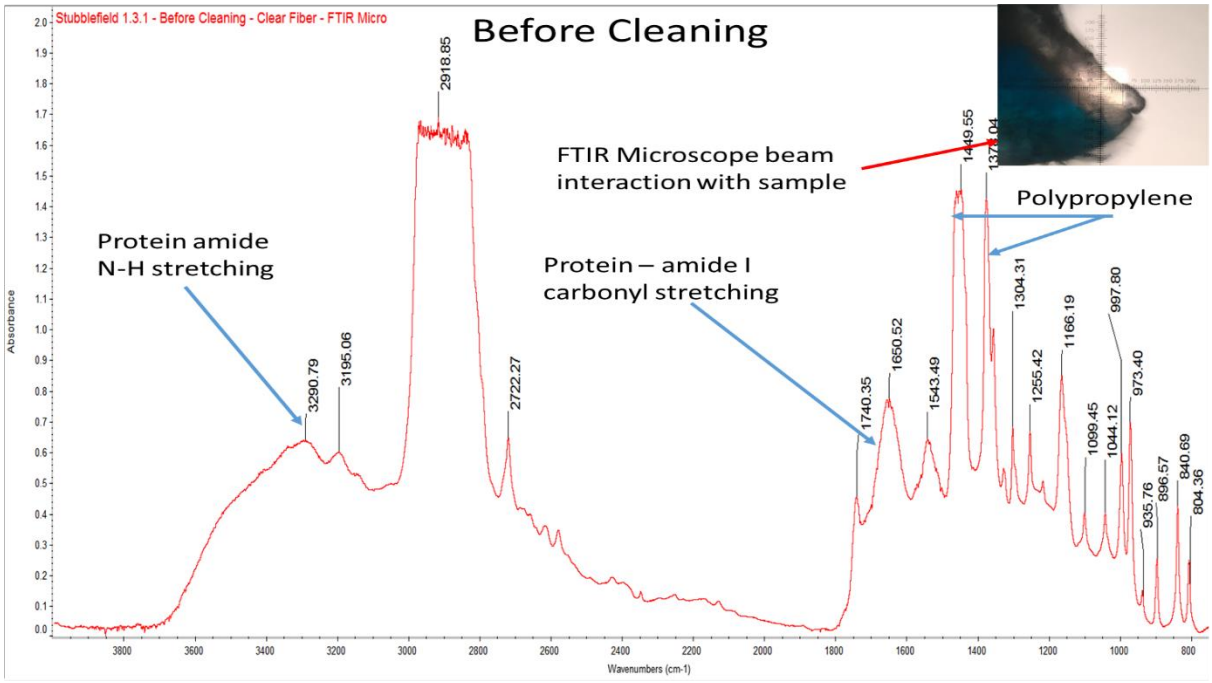

Figure 6. Stubblefield 1.3.1 – Clear fiber FTIR before cleaning

An FTIR spectrum of tissue located between explant fibers was also collected and compared to the spectrum of Collagenase (a protein control) and they are included in Figure 7, demonstrating the overlap in the N-H and amide I peaks. The tissue spectrum was in turn overlaid with the spectrum of fiber before cleaning demonstrating the amide I peak is present in both tissue and Prolene fiber (Figure 8).

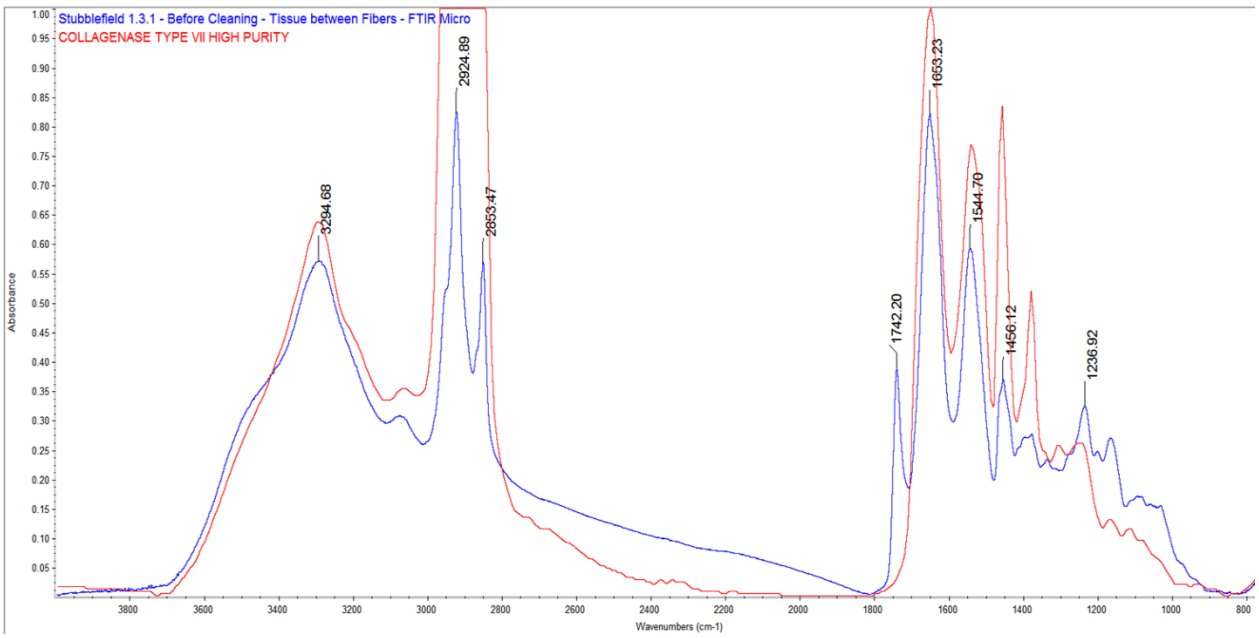

Figure 7. Stubblefield 1.3.1 – Tissue between fibers before cleaning overlaid with a Collagenase reference spectra

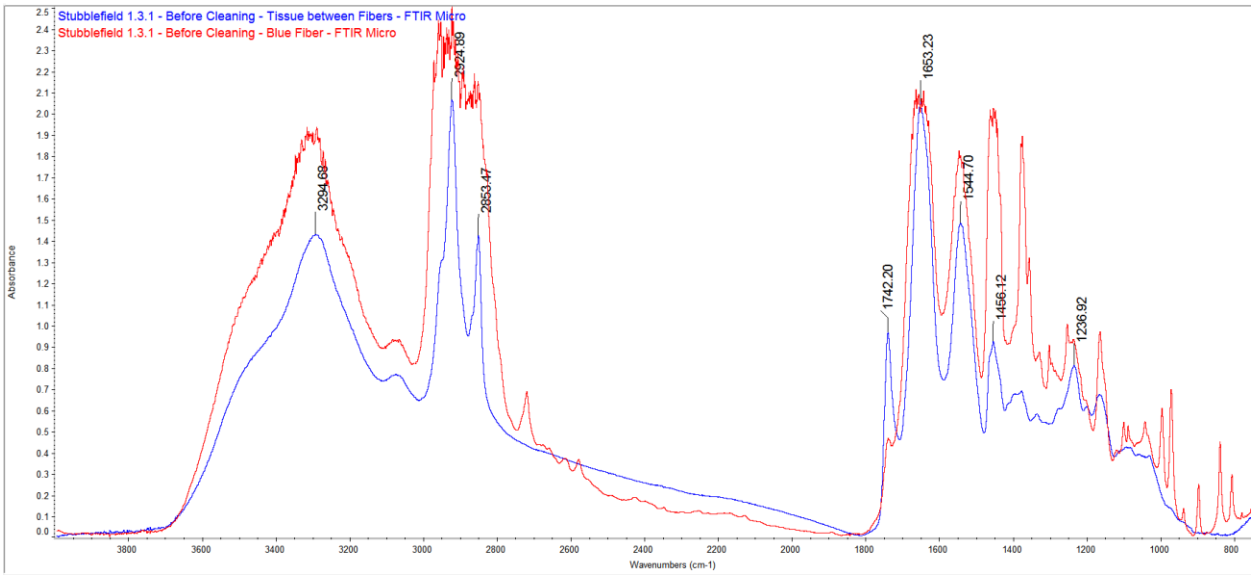

Figure 8. Stubblefield 1.3.1 – FTIR of Tissue between fibers before cleaning overlaid with Blue Fiber before cleaning

Exemplar and explant samples were likewise examined before and after the cleaning steps described. FTIR data demonstrates the progression of protein removal after each cleaning step for the explant's blue and clear Prolene fibers (Figure 9 and 10). This was confirmed via light microscopy and SEM (see the series of images in Figures 12, 13, and 14 depicting the progressive explant cleaning).

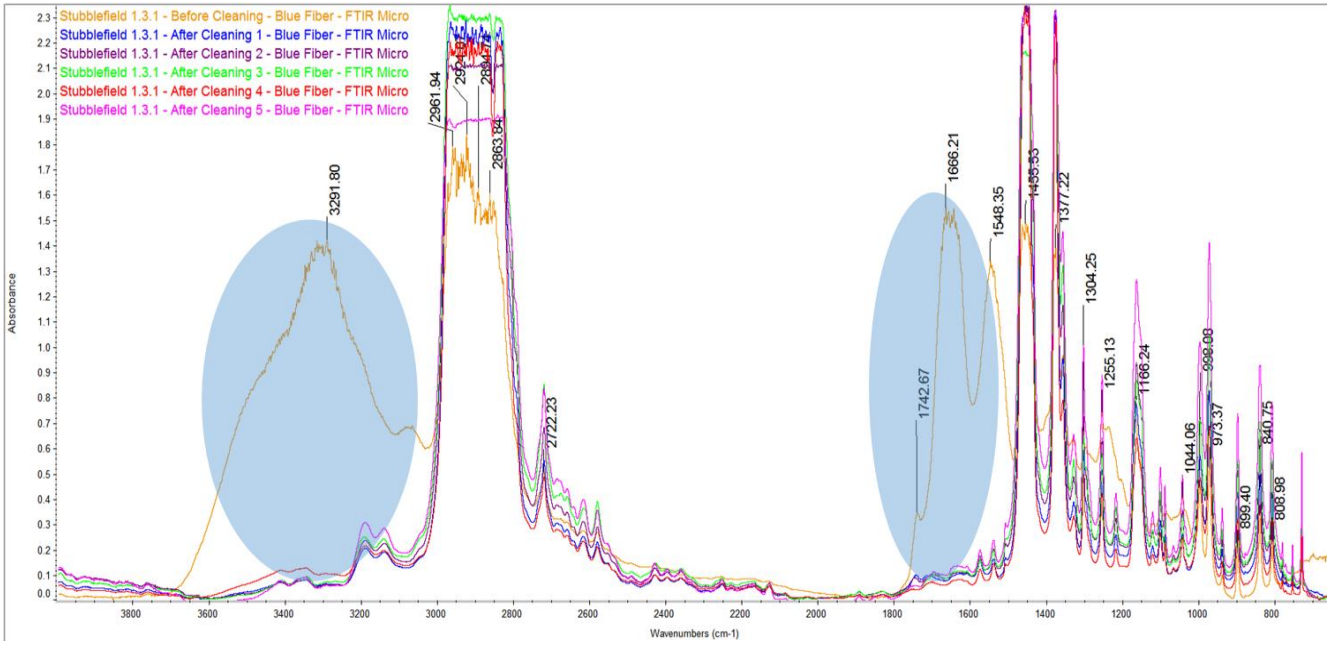

Figure 9. Stubblefield 1.3.1 – FTIR of Blue Fiber after cleaning steps

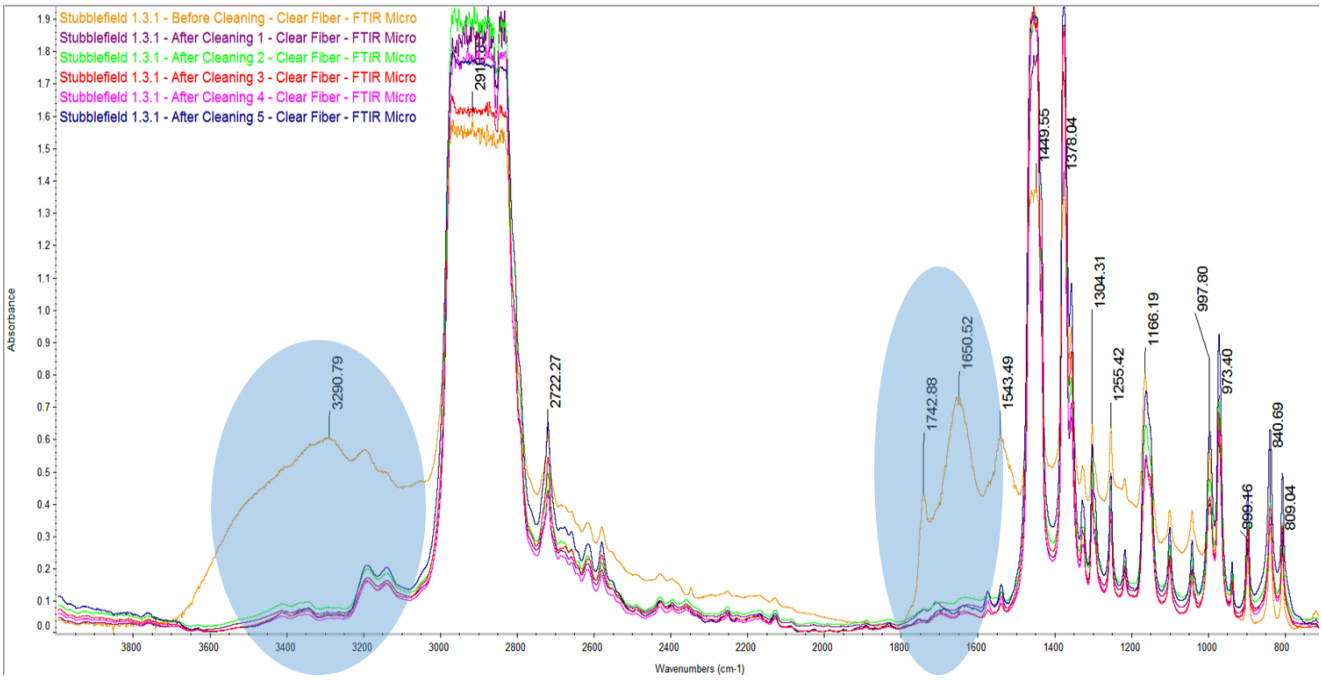

Figure 10. Stubblefield 1.3.1 – FTIR of Clear Fiber after cleaning steps

The FTIR data proves surfaces of uncleaned explants are covered with adsorbed proteins. Collagen and other proteins chemically react with formalin during the fixation process to form a tightly adhered, hard, brittle, insoluble composite polymeric sheath around explant fibers. Consequently, in order to remove the crosslinked protein layer one must utilize knowledge of the protein-formaldehyde chemical reaction mechanism of formation that creates the crosslinked product. The cleaning process was developed

utilizing knowledge of the protein-formaldehyde crosslinking chemistry, and therefore is an effective cleaning process. This has been affirmed by FTIR analyses of cleaned Prolene explant fibers, and LM as well as SEM microscopy noted in the LM and SEM images of Figures 12, 13, and 14. An example of the effectiveness of the cleaning process is shown in the FTIR spectral overlay of Figure 11, comparing a Gynemesh exemplar to the cleaned Stubblefield 1.3.1 explant.

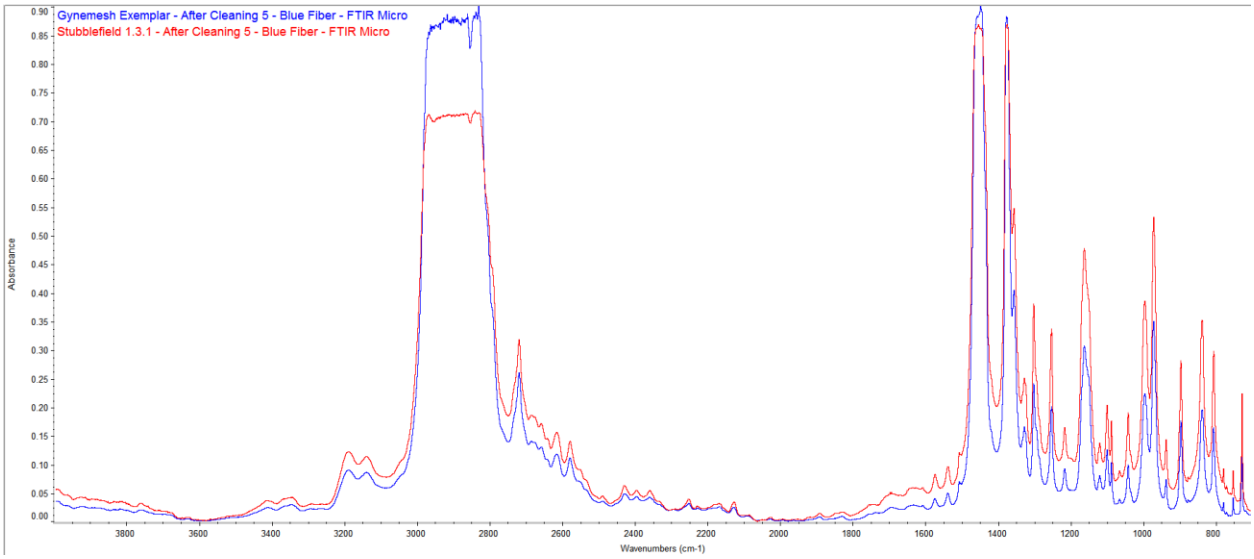

Figure 11. Stubblefield 1.3.1 and Gynemesh Exemplar – FTIR of Blue Fibers after cleaning steps

The light microscopy images of Figure 12 illustrate the overall appearance of the explant before cleaning and after each of the cleaning intervals previously discussed. Higher magnification light microscopy images are also included in Figure 13 demonstrating the successive removal of tissue during the cleaning protocol.

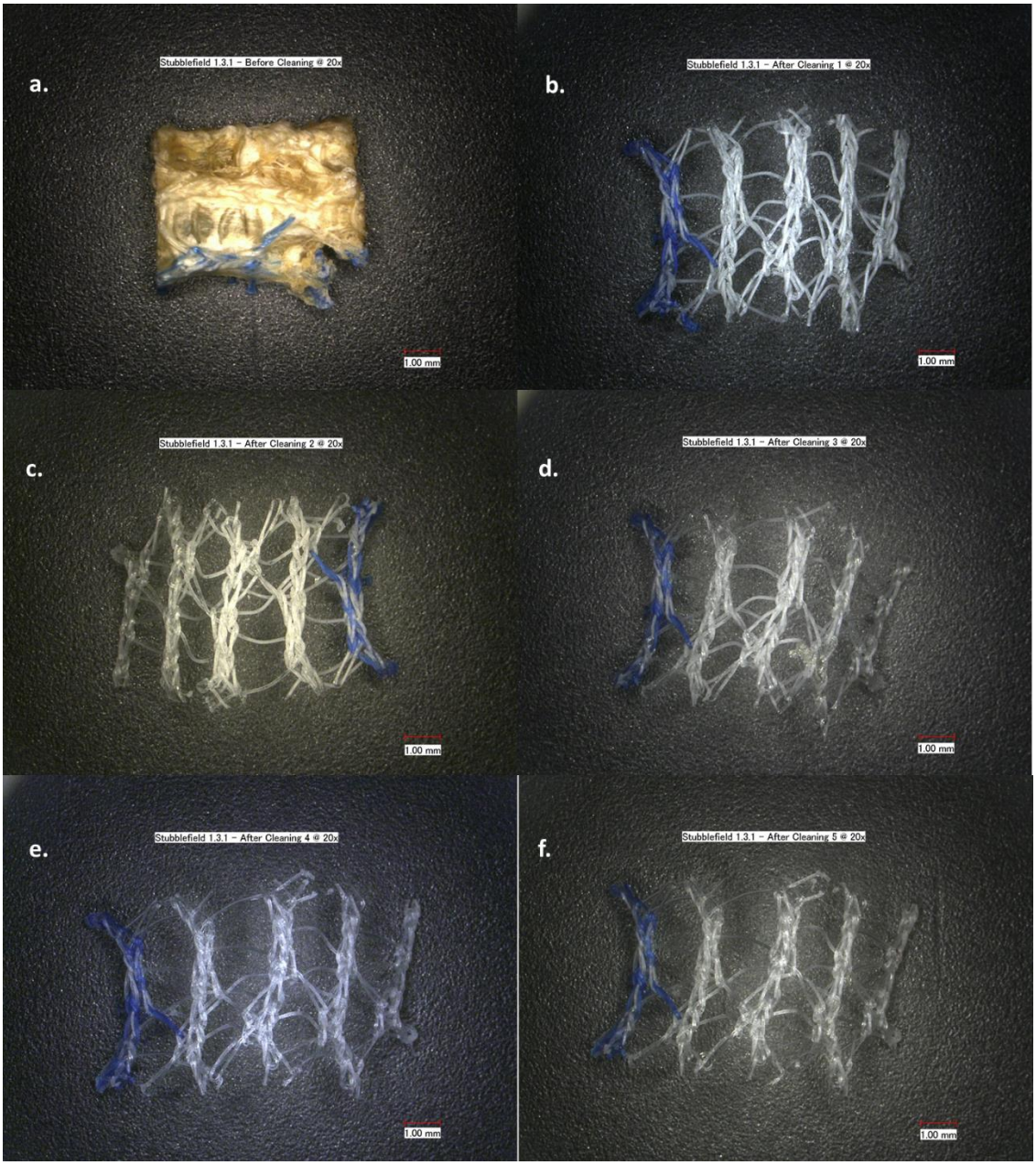

Figure 12. a., b., c., d., e., and f. – Stubblefield 1.3.1 Light Microscopy after cleaning steps

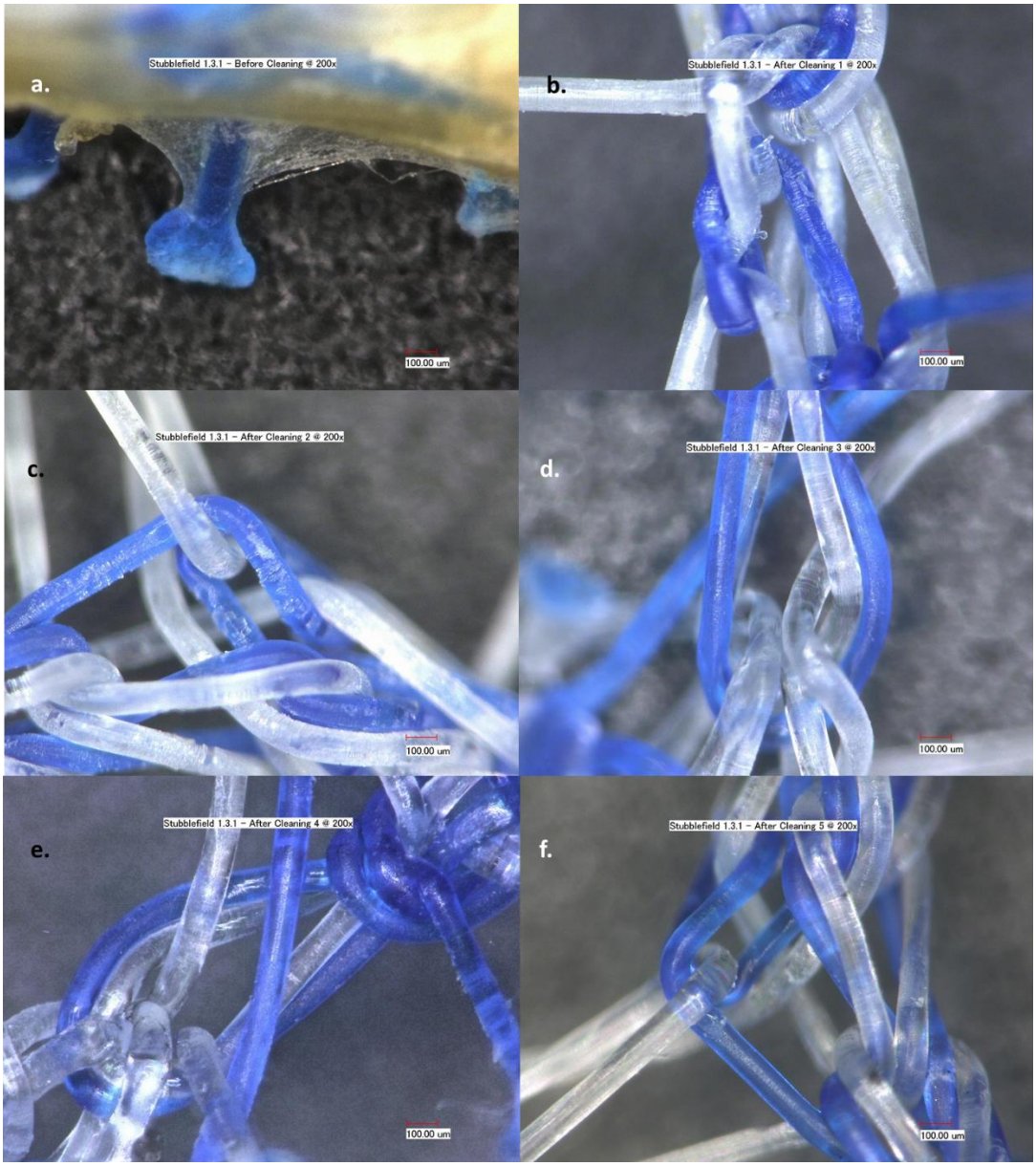

Figure 13. a., b., c., d., e., and f. – Stubblefield 1.3.1 Light Microscopy after cleaning steps

SEM images at various cleaning stages depicts both the progression of explant fiber cleaning (Figure 14 b) and defines the cracked surface appearance of the fibers and its origin. The easily observable pattern of the formalin-protein composite coating (Stubblefield 1.3.1; SEM 03) perfectly describes cohesive failure of the coating and in Figure 14 d, partial adhesive failure of this same formalin-protein composite layer surrounding Prolene.

Furthermore, the cleaning process demonstrates visually fiber surface degradation did not occur. The SEM images of Figure 14 shows partial removal of the proteinaceous

shell surrounding the fiber. The cleaned fibers in Figure 14 continue to possess extrusion lines created during manufacture. If the surface of the Prolene fibers had degraded, as postulated by plaintiff's expert, the extrusion lines would degrade during this process and would no longer be visible – that is not the case we observed. Therefore, degradation of the Stubblefield implant did not occur.

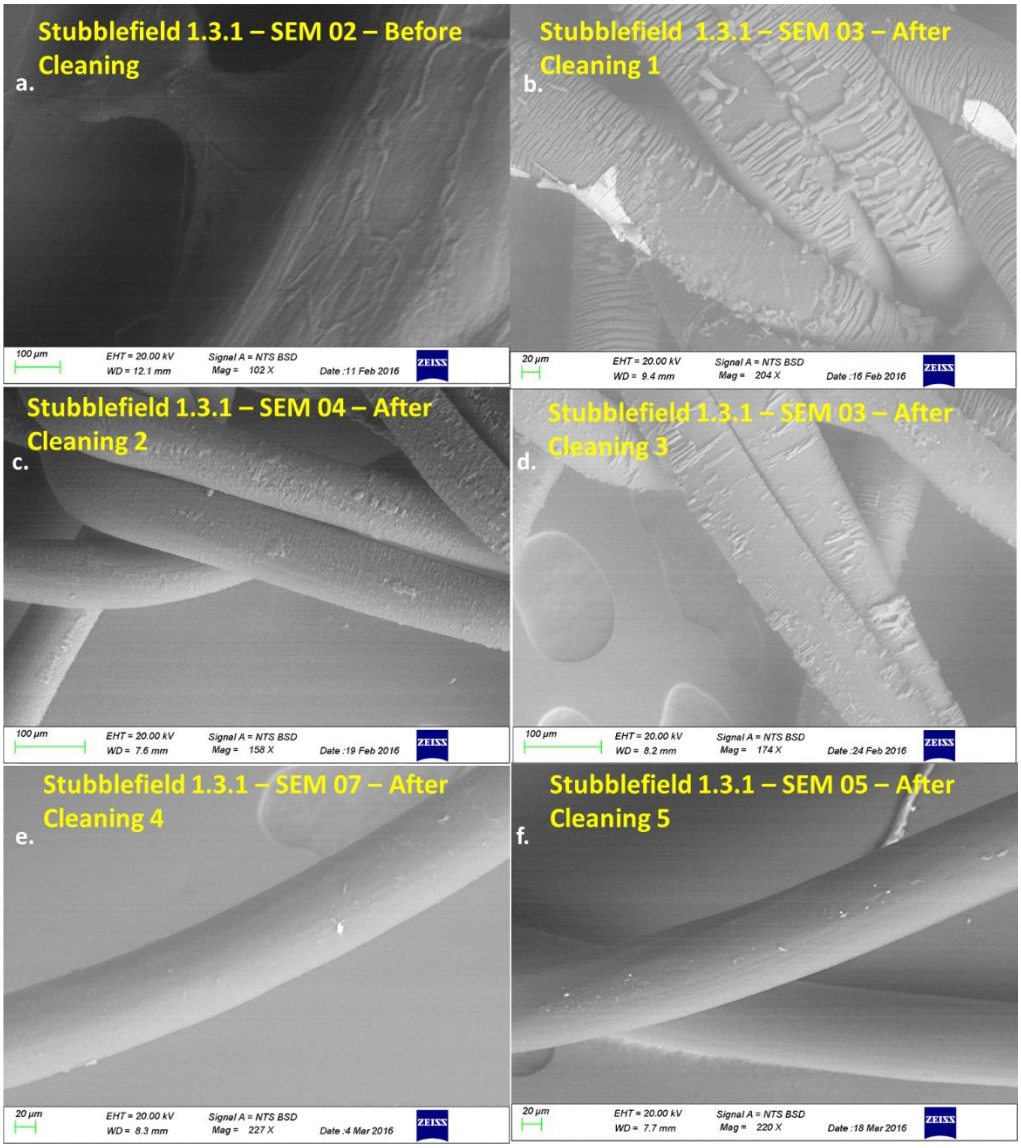

Figure 14. a., b., c., d., e., and f. – Stubblefield 1.3.1 SEM Micrographs after cleaning steps

I reserve the right to supplement this initial report and analysis, create additional exhibits as necessary to illustrate my testimony based upon the receipt of additional information, documents and materials, and to revise this report following the receipt of additional information and/or materials that have not yet been made available. Appendices of all FTIR, LM, and SEM data which I relied upon will be supplemented.

Shelby F. Thames, Ph.D.

[1] Kong, J. and Shaoning, Y., Fourier Transform Infrared Spectroscopic Analysis of Protein Secondary Structures, Acta Biochimica et Biophysica Sinica 2007, 39(8): 549-559

[2] Notter, S. J., Stuart, B. H., Rowe, R. and Langlois, N. (2009), The Initial Changes of Fat Deposits During the Decomposition of Human and Pig Remains. Journal of Forensic Sciences, 54: 195–201. doi:10.1111/j.1556-4029.2008.00911.x

[3] Stuart, Barbara, H. (2004) Infrared Spectroscopy: Fundamentals and Applications, Analytical Techniques in the Sciences, ISBN: 9780470854280, Wiley